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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,213	12/04/2001	Fred H. Burbank	R0367-00201	7928

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EXAMINER
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FOREMAN, JONATHAN M

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 12/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	Application No. 10/010,213	Applicant(s) BURBANK ET AL.	
	Examiner Jonathan ML Foreman	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 September 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 3-11, 13, 15, 19-22, 24-29, 31, 35, 36, 39, 40, 43, 45, 46, 49-55 and 57-74 is/are pending in the application.

4a) Of the above claim(s) 3-11, 13, 15, 19-22, 24-29, 31, 35, 36, 39, 40, 43, 45, 46, 49, 50, 52, 54, 55, 57-60 is/are withdrawn from consideration.

- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 51, 53 and 61-74 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
 1. ☐ Certified copies of the priority documents have been received.  
 2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                            | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

## DETAILED ACTION

### *Claim Objections*

1. Claims 51 and 53 are objected to because of the following informalities: There is insufficient antecedent basis for “the bendable legs” in line 11 of claim 51. There is insufficient antecedent basis for “said hinged linkage” in lines 2 – 3 of claim 53. Appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 51, 53, 61 - 64, 69, 70 and 74 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,059,734 to Yoon.

In regards to claims 51 and 53, Yoon discloses a tissue acquisition instrument including a distal end (116) for entry into a patient's body; a cutting element (287) which has a contracted configuration (Figure 27) and an expanded configuration (Figure 26) for separating tissue from the body site; and a mechanical fixation element (148) disposed proximal to the distal end (Figure 19) having an expanded configuration for securing the instrument at a desired location (Col. 10, lines 49 – 59), in order to insure that the instrument remains in place during a tissue acquisition procedure and which has a fully retracted configuration with a transverse dimension of the bendable legs which is smaller than the expanded configuration. The tissue specimen has a transverse dimension and

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said hinged linkage is configured to have a transverse dimension smaller than the transverse dimension of the tissue specimen (Figure 31).

In regards to claims 61 - 64, Yoon discloses an instrument including an elongated shaft having a longitudinal axis and a distal end (160) adapted for entry into a patient's body; a tissue cutting element (162) disposed on the elongated shaft proximal the distal end for cutting tissue surrounding the shaft which is capable of cutting along its length and which is longitudinally aligned; and a mechanical fixation assembly (148) on the elongated shaft proximal the distal end and has a pair of outwardly bendable legs for securing tissue (Col. 10, lines 49 – 59). The bendable legs have a first and second leg segment. The legs have a transverse dimension smaller than the transverse dimension of the tissue specimen.

In regards to claims 69, 70 and 74, Yoon discloses an elongated shaft having a longitudinal axis and a distal end (160) for entry into a patient's body; and a mechanical fixation assembly (148) configured to be disposed within the specimen when it is separated from the surrounding tissue (Figure 31), the mechanical fixation assembly being on the elongated shaft proximal the distal end (Figure 19) which has at least one pair of outwardly bendable legs for securing the instrument within the patient's body; and a tissue separation element that is radially expandable having a contracted configuration (Figure 27) for delivery within a patient and an expanded configuration (Figure 26) for cutting tissue.

4. Claim 69 is rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,423,770 to Yoon.

In regards to claim 69, Yoon discloses an elongated shaft having a longitudinal axis and a distal end (140) for entry into a patient's body; and a mechanical fixation assembly on the elongated

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shaft proximal the distal end which has at least one pair of outwardly bendable legs for securing the instrument within the patient's body (Col. 14, lines 9 – 20); and a tissue separation element (138).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 65 - 68 rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,423,770 to Yoon in view of US Patent No. 5,947,964 to Eggers et al.

In regards to claims 65 – 68, Yoon discloses a tissue acquisition instrument including an elongated shaft with a distal end having a cutting element (140) adapted for entry into a patient's body; and a mechanical fixation element disposed on the distal end for securing the instrument at a predetermined location (Col. 14, lines 9 – 20). The mechanical fixation element includes a pair of bendable legs (139) with each leg having a hinged (141) linkage. Yoon discloses a cutting element (140), but fails to disclose an electrosurgical cutting element. However, Eggers et al. teaches a needle adapted for entry into a patient's body having an electrosurgical cutting element (29; Col. 6, line 49) located on the distal end an elongated shaft. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the cutting element as disclosed by Yoon to be an electrosurgical cutting element as taught by Eggers et al. in order to simultaneously cut and cauterize while inserting the instrument into the tissue.

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7. Claims 71 – 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,059,734 to Yoon as applied to claim 70 above, and further in view of US Patent No. 5,947,964 to Eggers et al.

In regards to claims 71 - 73, Yoon discloses a tissue acquisition instrument including an arcuate cutting element (287) configured to be rotated about a longitudinal axis when cutting tissue. However, Yoon fails to disclose an electrosurgical cutting element. However, Eggers et al. teaches a needle adapted for entry into a patient's body having an electrosurgical cutting element (See Abstract). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the cutting element as disclosed by Yoon to be an electrosurgical cutting element as taught by Eggers et al. in order to simultaneously cut and cauterize the tissue while collecting the tissue.

### ***Response to Arguments***

8. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be

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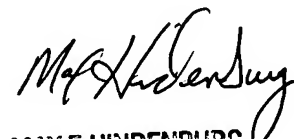
calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
JMLF

  
MAX HINDENBURG  
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